UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

In re MiMedx Group, Inc. Securities Litigation	**Civil Action No 1:13-cv-03074-TWT** **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Lead Plaintiff Tim Kelly ("Plaintiff"), individually and on behalf of all other persons similarly situated, alleges in the Amended Complaint (the "Complaint") the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things: (a) review of Securities and Exchange Commission ("SEC") filings by MiMedx Group, Inc. ("MiMedx" or the "Company"), (b) review and analysis of defendants' public documents, conference calls and press releases; (c) review and analysis of securities analysts' reports and advisories concerning the Company; (d) information readily obtainable on the Internet; (e) interviews of several witnesses with personal knowledge of the facts; and (f) consultation with

an advisor on medical, scientific and regulatory issues concerning MiMedx's products and applicable Food and Drug Administration ("FDA") regulations.

Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all purchasers of MiMedx common stock between March 29, 2012 and September 4, 2013, inclusive (the "Class Period"). Plaintiff seeks to pursue remedies against MiMedx and certain of its most senior executives under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder. The "Individual Defendants" include MiMedx Chairman, CEO and President, Parker "Pete" H. Petit ("Petit"), MiMedx CFO Michael J. Senken ("Senken"), and MiMedx COO William C. Taylor ("Taylor").

2. MiMedx is a small pharmaceutical company that manufactures and distributes a number of products using amniotic tissue, which products MiMedx claims treat chronic wounds. The Company gets the amniotic tissue from placenta

donations from women who have given birth via c-section and choose to donate their placentas to MiMedx. The Company then collects amniotic tissue from the placentas for use in its products. The amniotic tissue from the placentas is ground up into injectable products, which MiMedx manufactures and sells to distributors. As of 2012, placenta-based products accounted for 95% of MiMedx's revenue.

3. MiMedx has been able to generate significant revenues from these products by manufacturing and distributing them without FDA approval. MiMedx did so by falsely claiming that these products were not subject to FDA scrutiny because they were "minimally manipulated" (i.e. did not undergo much processing) and therefore were subject to Section 361 of the Public Health Service Act ("Section 361"), which provides that products made from tissues can be sold without premarket FDA scrutiny so long as they comply with four criteria, one of which is referred to as "minimal manipulation" (discussed further below).

4. A product that does not satisfy Section 361 is automatically considered a biologic or a drug which requires intense premarket scrutiny and can involve over a decade of expensive research. After MiMedx acquired a company that manufactured products made from amniotic tissue and MiMedx began selling these products without premarket FDA scrutiny and its attendant costs, MiMedx's

stock price surged from around $1 at the start of 2012 to a high of $7.73 in the summer of 2013.

5. Against this backdrop, the Company's Class Period annual reports and public statements assured investors that its injectable products satisfied all of the criteria of Section 361 and were not subject to FDA regulation.

6. On August 28, 2013 the FDA issued an "Untitled Letter" to MiMedx and its distributors stating that its key products did not meet the minimal manipulation criteria under Section 361 due to the "micronization process which alters the original, relevant characteristics of the structural tissue, relating to the tissue's utility for reconstruction, repair or replacement."

7. When news outlets reported that the FDA posted this "Untitled Letter" on its website the Company's stock dropped from $6.06 per share to $3.85 per share on September 4, 2013, on extraordinary volume.

8. The FDA's untitled letter resulted from a July 30, 2012-August 1, 2012 FDA "directed inspection" of MiMedx's manufacturing facilities in Kennesaw, GA. This "directed inspection" was specifically requested by the FDA Center for Biologics Evaluation and Research to evaluate the status of MiMedx's amniotic membrane tissue products under Section 361. At the inspection, the FDA

inspector specifically inquired into MidMedx's basis for the claimed Section 361 exemption from FDA approval. The FDA further put MiMedx on notice that it was scrutinizing its claim to a Section 361 exemption in a December 4, 2012 letter to Defendant Taylor which summarized the inspection. That letter further put Defendants on notice that the FDA might take action against MiMedx and prohibit any further sales of its amniotic membrane tissue products without MiMedx going through the time consuming and expensive process of obtaining FDA approval.

9. MiMedx continues to maintain that the products cited in the FDA's "Untitled Letter" meet the minimal manipulation criterion, and continues to market its products without FDA approval. However, the Company has been in talks with the FDA and has proposed to the FDA that it will open an Investigational New Drug ("IND") application, conduct clinical trials and file a Biologics License Application ("BLA"), and enter into negotiations with the FDA on a plan to transition its products to licensed biological products. MiMedx has admitted that if it cannot agree on a transition plan with the FDA it "may have to remove the micronized products from the market." *See* MiMedx Preliminary Prospectus Supplement, December 19, 2013 filed with the SEC Pursuant to Rule 424(b)(5) at S-3-S-4, available at:

http://www.sec.gov/Archives/edgar/data/1376339/000119312513465846/d640968d424b5.htm. As discussed below clinical development and filing a BLA is a very lengthy and very costly process, and once it is complete there is still no guarantee that the FDA will approve the product.

JURISDICTION AND VENUE

10. Jurisdiction is conferred by §27 of the Exchange Act. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

11. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b) as the Company conducts business in this district and its headquarters are located in this district. Defendants' public statements that are alleged to be false and misleading herein were transmitted into this District and relied upon by investors.

12. In connection with the acts alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

13. Court appointed Lead Plaintiff Tim Kelly, as set forth in his PSLRA Certification previously filed with the Court and incorporated by reference herein, purchased the common stock of MiMedx during the Class Period and has been damaged thereby. Plaintiff Kelly is a citizen of Port Orchard Washington, Kitsap County, Washington.

14. MiMedx is a Florida Corporation headquartered in Kennesaw, Georgia.

15. During the Class Period MiMedx's common stock was actively traded on the NASDAQ, under ticker MDXG.

16. Defendant MiMedx, together with its subsidiaries, operates as an integrated developer, manufacturer, and marketer of patent protected regenerative biomaterial products and allografts processed from human amniotic membranes. Its biomaterial platform technologies include HydroFix and CollaFix device technologies; and AmnioFix and EpiFix tissue technologies.

17. In January of 2011, MiMedx acquired Surgical Biologics, Inc. Thereafter, MiMedx began producing a number of treatments using amniotic

tissue, which it says can treat chronic wounds. As of 2012, placenta-based products accounted for 95% of MiMedx's revenue.

18. Defendant Petit was and is the Company's Chairman of the Board and CEO at all relevant times. Petit joined MiMedx in 2009 as the Company's Chairman and CEO. Petit is currently being prosecuted by the SEC for insider trading in connection with the stock of a different company. *See SEC v. Arrowood and Petit*, 12-cv-00082.

19. Defendant Senken was and is the Company's CFO since January 2010.

20. Defendant Taylor was and is the Company's President and COO at all relevant times. Taylor has been the Company's President and COO since September 2009 and has been a Company director since October 2011.

21. Petit, Senken, and Taylor are referred to herein as the "Individual Defendants." MiMedx and the Individual Defendants are referred to herein, collectively, as "Defendants."

22. Each of the Individual Defendants:

(a) directly participated in management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was aware of or recklessly disregarded the fact that false and misleading statements were being issued concerning the Company; and

(f) approved or ratified these statements in violation of the federal securities laws.

23. As officers, directors and controlling persons of a publicly-held company whose common stock is and was registered with the SEC pursuant to the Exchange Act and was traded on the NASDAQ and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate accurate and truthful information promptly and to correct all previously issued statements that had become materially misleading or untrue to enable the market price of the Company's publicly-traded stock to reflect truthful and accurate information.

24. MiMedx is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

25. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to MiMedx under the *respondeat superior* and agency principles.

SUBSTANTIVE ALLEGATIONS

A. MiMedx's Business

26. On January 5, 2011 MiMedx officially acquired Surgical Biologics, LLC ("Surgical Biologics") in an effort to expand its biomaterials product lines. *See* MiMedx Form 10-K for the fiscal year ended December 31, 2011 at 66, filed with the SEC on March 29, 2012. ("2011 10-K")

27. With the acquisition of Surgical Biologics, MiMedx acquired amniotic allograft tissue products. According to MiMedx's website, "this strategic acquisition brought together amnion tissue processing technology with MiMedx's experienced management team and extensive distribution network in order to position the company for market opportunities across multiple areas of medicine.

Surgical Biologics developed allografts and other products processed from human amniotic membrane that can be used in a wide range of medical applications."

28. The acquisition of Surgical Biologics and its corresponding tissue products accounted for a substantial portion of MiMedx's stellar revenue growth. MiMedx's 2012 Annual Report filed on Form 10-K with the SEC states that "total revenue increased from approximately $7,760,000 in 2011 to $27,054,000 in 2012. The increase in revenue as compared with the prior year is due primarily to increased sales of our amniotic membrane tissue products EpiFix and AmnioFix." *See* MiMedx Form 10-K for the fiscal year ended December 31, 2012 filed with the SEC on March 15, 2013 at 42 ("2012 10-K").

29. MiMedx's primary products are AmnioFix ("AmnioFix") and EpiFix ("EpiFix"). MiMedx describes AmnioFix as "a composite amniotic tissue membrane minimally manipulated to protect the collagen matrix and its natural properties. AmnioFix reduces scar tissue formation near or on the dura, reduces inflammation in the surgical site, enhances healing, and acts as a barrier to provide a dissection plane. Human amniotic membrane comprises the innermost layer of the placenta and lines the amniotic cavity." MiMedx makes AmnioFix in a wrap form and an injectable form ("AmnioFix Injectable"). MiMedx's "AmnioFix

Injectable Product Overview" states that "AmnioFix Injectable…is supplied in a powder form so the benefits of the tissue may be delivered through an injection." Similarly, according to MiMedx's website EpiFix "is a human amniotic membrane allograft" also available to be mixed with saline to form and injectable or used as a dry powder.

30. MiMedx describes itself as "the global premier processor, marketer and distributor of human amniotic tissue."

31. MiMedx obtains this human amniotic tissue for use in its products, strictly through donations via its "Give the Gift of Healing" placenta donation program which "provides an opportunity for mothers delivering full-term Caesarean section births to donate their placenta for medical uses. The placenta is normally discarded as medical waste."

B. Regulatory Background

32. In connection with Plaintiff's investigation, Plaintiff consulted with a regulatory expert, Nancy Chew. Nancy Chew has provided Plaintiff with scientific and regulatory advice and guidance and an opinion as to MiMedx's Class Period statements. Nancy Chew is the president of Regulatory Affairs North America, Inc. In this capacity, she guides companies through the regulatory process for

drugs and devices. She has been doing so for over thirty-five years. She has published journal articles, book chapters, and various magazine articles and columns on the regulatory approval process. Her resume is attached as Exhibit 1 to this Complaint.

33. In February 1997, the Food and Drug Administration ("FDA") provided a regulatory framework for human tissues intended for transplantation, and in 1998 the FDA's Tissue Regulatory Group began making recommendations about how tissue products, such as MiMedx's, would be regulated.

34. The FDA has specific regulations governing human cells, tissues and cellular and tissue products or "HCT/Ps." An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. MiMedx's products are HCT/P's, as they are made from human tissue. HCT/P's are a special category of biological products and are not exempt from the stringent FDA review process for safety and effectiveness under a drug, device or biological product marketing application.

35. However, certain HCT/P's are not subject to the stringent FDA review process for safety and effectiveness under a drug, device or biological product marketing application. Such products are regulated under Section 361 of the

Public Health Service Act and are referred to as "361 HCT/P's". While 361 HCT/P's do not require FDA approval, the company that processes and sells the 361 HCT/P's is nevertheless required to register with the FDA, comply with FDA regulations regarding labeling, record keeping, donor eligibility and screening and testing, and to process the tissue in accordance with established Good Tissue Practices ("GTP") and report any adverse events.

36. To be considered a 361 HCT/P and thus be exempt from FDA approval, a product must meet four criteria, one of which is that the product must be "minimally manipulated.[1]"

37. In September of 2006, the FDA published a Guidance Document on minimally manipulated structural tissues. *See Guidance for Industry and FDA*

[1] The additional criteria for classification as a 361 HCT/P are that the product must: be intended for homologous use only, as reflected in labeling, advertising, or other indications of the manufacturer's objective intent; not be combined with a drug or device, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of the water, crystalloids, or sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and not have a systemic effect and not be dependent on the metabolic activity of living cells for its primary function except if for autologous use, allogenic use in a first-degree or second-degree blood relative, or reproductive use. 21 CFR 1271.10(a). A product must meet all four of these criteria to be considered a 361 HCT/P.

Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update, attached hereto as Exhibit 2 ("FDA Guidance Document").

38. FDA regulations define "minimal manipulation" for structural tissue as "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 CFR 1271.3(f)(1).

39. Ms. Chew gives the following common sense example of taking a piece of tissue paper, which is used as a covering, and grinding it up into small microscopic pieces. The tissue paper would be altered because its tensile strength would be destroyed and its structural integrity as one continuous piece of paper would be changed. In the above example, the grinding up of the tissue paper *cannot* be defined as "minimal manipulation" because the processing (grinding) of the tissue paper alters its original relevant characteristics.

40. According to the FDA Guidance Document, a tissue characteristic is "original" if it is present in the tissue of the donor. A tissue characteristic is "relevant" if it could have a meaningful bearing on how the tissue performs when utilized for reconstruction, repair, or replacement.

41. Accordingly, the FDA's determination of whether the structural tissue is eligible for regulation solely as a 361 HCT/P encompasses a consideration of all of the potential effects, both positive and negative, of the alteration of a particular characteristic on the utility of the tissue for reconstruction, repair, or replacement. "Once the FDA has determined, based on the data and information before it, that processing has altered the original relevant characteristic of a structural tissue, and that the characteristic is relevant in that it has a potential effect on the utility of the tissue for reconstruction, repair or replacement, *the agency has considered the tissue to be more than minimally manipulated and not eligible for regulation solely under Section 361 of the PHS Act. In such a case the structural tissue will be regulated as a drug, device and/or biological product under the Federal Food, Drug, and Cosmetic Act and/or section 351 of the PHS Act.*" FDA Guidance Document at 3, (emphasis added) – requiring that it be subject to the expensive and time consuming process of obtaining FDA approval.

42. The FDA Guidance Document sets forth the means by which a manufacturer or developer of a tissue based product can ascertain whether such HCT/P product will be regulated solely under Section 361: by contacting the Office of Cellular, Tissue and Gene Therapies Tissue Reference Group for an

initial determination. A manufacturer or distributor may also seek a formal determination of the classification or assignment of a particular product through the ***Request for Designation*** ("RFD") process. *Id*.

43. Despite claiming that their AmnioFix and EpiFix products were regulated solely as 361 HCT/P's, MiMedx never sought an initial determination from the FDA as to whether their products qualified as 361 HCT/P's. MiMedx also never sought a formal determination through the RFD process.

44. The FDA's Tissue Reference Group ("TRG"), which was established fourteen years ago specifically so companies developing structural tissue products like MiMedx could receive opinions on how their products should be categorized prior to their commercial sale, made the following public recommendation in September 2006: "Allogeneic decellularized dehydrated amniotic membrane advertised for improved wound healing of venous ulcers on the leg in conjunction with compression therapy is considered to be a biological product subject to investigational new drug applications (INDs) and biologic license applications (BLAs) because processing would have a meaningful bearing on how the tissue performs thereby altering the original relevant characteristics of the HCT/P and constituting more than minimal manipulation." This is analogous to MiMedx's

product- made from amniotic tissue and used for wound healing. This recommendation made it obvious to MiMedx that its products were *not* minimally manipulated and therefore did *not* qualify at 361 HCT/P's. Moreover, this further shows that other companies that market amniotic tissues take advantage of this FDA service and have been denied HCT/P status for their products. This is the likely reason that MiMedx did not take advantage of this FDA service: it did not want the production and sale of its primary revenue producing products to get shut down before it had a chance to expand its revenue base and build market share. MiMedx knew that if its production and distribution of AmnioFix and EpiFix were shut down it would be forced to undergo the tremendous expense of completing a Biologics License Application, which would have frozen its stock market promotion scheme in its tracks.

45. According to a regulatory consultant interviewed by Plaintiff's investigator familiar with MiMedx's situation, MiMedx will likely have to expend at least $10 million to complete a Biologics License Application (BLA) for its products alone, and such a process would take approximately 4-5 years. In addition, clinical development for a product usually requires the expenditure of hundreds of millions of dollars.

C. The FDA's Establishment Inspection Report of Surgical Biologics

46. From July 30, 2012 to August 1, 2012 an FDA investigator from the FDA's Atlanta District Office conducted an inspection of MiMedx's Surgical Biologics unit in Kennesaw, Georgia (the "2012 Inspection"). On December 4, 2012, the FDA's Atlanta District Office sent a copy of the establishment inspection report or ("EIR") for the 2012 Inspection to MiMedx's CEO Bill Taylor. The 2012 Inspection was conducted by FDA investigator Kimberly Delk-Brooks. A copy of the EIR is attached to this Complaint as Exhibit 3.

47. The EIR states that the 2012 Inspection of Surgical Biologics was a "directed inspection." Such an inspection is conducted to gather information, which the FDA inspector then sends to the Center for Biologics Evaluation and Research ("CBER") which analyzes the information collected and then makes a determination based upon the information collected and the interview conducted. The CBER consists of individuals who actually regulate tissues and cells, whereas the FDA inspector gathers information and conducts an interview of management and/or employees at a given facility to provide CBER with information.

48. The FDA's inspection of MiMedx previous to the 2012 Inspection was conducted in 2011, shortly after Mimedx acquired Surgical Biologics, Inc. and

prior to the release of MiMedx's AmnioFix and EpiFix products on the market. *See* EIR at page 1 ("The previous inspection of this Human Cells, Tissues, and Cellular Tissue-Based Products HCT/Ps's firm was an initial inspection conducted on 2/28-3/1/11") and page 2 ("There have been several changes to the firm's operations since the previous inspection. The firm launched their Amniofix injectable product (as well as 3 private label versions for distributors) approximately 3-4 months after the conclusion of the previous inspection").

49. The purpose of the 2012 Inspection was to determine the status of the Company's Amniofix Injectable product and to collect information to forward to CBER. CBER would then determine whether the Company was properly classifying its products. The 2012 Inspection was a "directed" inspection insofar as the FDA inspector was directed by CBER to conduct a specific inspection of AmnioFix and to collect information regarding the manufacture of the Company's AmnioFix product and then forward that information to CBER.

50. The EIR states that "Information regarding the firm's Amniofix Injectable product, which was rolled out approximately August 2011 was *collected and forwarded to the CBER for review* (emphasis added)." EIR at page 3. In collecting and forwarding information to CBER, the FDA investigator does *not*

make any determination as to the status of a given product *vis a vis* whether it can properly be categorized as a Section 361 HCT/P. That determination is made at CBER by the TRG.

51. The EIR went on to describe MiMedx's products: "The firm manufactures a total of four injectable products made from amniotic membrane, which undergo the same processing as all of their amniotic membrane, graft products. Once the membrane sheet has been dehydrated, it will undergo cryo milling in order to grind the membrane down into micronized pieces…." The EIR noted MiMedx's own characterization of its products: "The firm considers their processing technique to be minimal manipulation of tissue and results in no viable cells after processing." EIR at 3.

52. The EIR also noted that during the 2012 Inspection the inspector had a close out discussion meeting with management and that "an FDA 483 was not issued at the conclusion of the inspection." EIR at 5.

53. An FDA 483 is a form issued at the conclusion of an inspection which notifies the company's management of conditions in its manufacturing and quality systems that deviate from expected norms. An FDA 483 indicates whether "conditions or practices observed would indicate that any food, drug, device or

cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health. *See* "Form 483 Frequently Asked Questions" available at: http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm. Accordingly, the issuance or non-issuance of an FDA 483 does *not* determine or opine on whether a given product meets the criteria for classification or status as a 361 HCT/P.

54. At the time the 2012 Inspection was conducted in July-August 2012 Defendants knew that the purpose of the 2012 Inspection was to collect information in order to determine the status of AmnioFix as a Section 361 HCT/P. This is so because when the FDA sends in an inspector into a given facility the FDA is required to communicate the purpose of its inspection. This serves the practical purpose of informing the facility manager to enable the facility manager to prepare the facility for inspection and alert employees who work there that an inspector will be conducting an inspection in their area.

55. Thus, as early as July 2012, Defendants were informed by the FDA inspector that CBER staff had requested a directed inspection concerning the status of AmnioFix as a qualified Section 361 HCT/P.

56. Indeed, shortly after the Company acquired Surgical Biologics and began marketing AmnioFix and EpiFix as 361 HCT/P's the Company's Vice President of Regulatory Affairs and Quality Assurance left the Company. The timing of this departure would be consistent with an ethical impasse regarding how the Company claims that its products are 361 HCT/P's.

57. Defendants knew that the FDA had never looked at its AmnioFix and EpiFix products to determine the propriety of classifying those products as 361 HCT/P's, because at the time of the 2011 FDA inspection the products did not exist.

58. Defendants also knew that the FDA was questioning the propriety of the products' Section 361 status, specifically whether the products met the "minimal manipulation" criterion, because this is the only one of the four criteria set forth in Section 361 that is noted in the EIR.

59. Defendants had no reasonable basis for their assertion that it "considers their processing technique to be minimal manipulation" because Defendants never sought a determination from the TRG. Defendants also knew that the FDA was scrutinizing its products to determine whether they in fact met the criteria for Section 361 because Defendants knew that the express purpose of

the 2012 Inspection was for the FDA inspector to collect additional data to provide CBER staff the information it needed to determine the applicability of Section 361 to its products.

60. Importantly, the EIR does *not* include a determination of whether MiMedx's products were properly classified as 361 HCT/P's; it merely summarizes the purpose of the 2012 Inspection and what was done during the Inspection. The 2012 Inspection itself and the EIR, which confirms in writing that CBER was in the process of evaluating MiMedx's assertion that its products were 361 HCT/P's, were both red flags which put Defendants on notice of the fact that the FDA was seriously questioning MiMedx's claim that the products at issue were 361 HCT/P's.

C. Defendants' Actionable Statements

61. The Class Period starts on March 29, 2012 when the Company filed with the SEC its annual report for the fiscal year ended December 31, 2011 on Form 10-K ("2011 10-K"). The 2011 10-K was signed by Defendants Petit, Senken, and Taylor. The 2011 10-K falsely states that the Company's AmnioFix and EpiFix products do not require approval from the FDA because they are regulated solely under Section 361 of the Public Health Service Act. The 2011 10-

K states in relevant part:

> Human Amniotic Tissue
>
> Our EpiFix® and AmnioFix® products are derived from human tissue. The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps") are not subject to any premarket clearance or approval requirements and are subject to less stringent post-market regulatory requirements.
>
> To be a 361 HCT/P, a product generally must meet all four of the following criteria:
>
> - It must be minimally manipulated;
> - It must be intended for homologous use;
> - Its manufacture does not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent; and
> - It does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.
>
> If an HCT/P meets all the above criteria, no FDA review for safety and effectiveness under a drug, device, or biological product marketing application is required. However, the processor of the tissue is required to register with the FDA, comply with regulations regarding labeling, record keeping, donor eligibility, screening and testing, process the tissue in accordance with established Good Tissue Practices, and report any adverse events. MiMedx continues to comply with all applicable regulations, as demonstrated by several FDA and other agency on-site audits.

62. The 2011 10-K underscored the importance of AmnioFix and EpiFix to MiMedx's business and reiterated that AmnioFix and EpiFix are 361 HCT/P's that are not more than "minimally manipulated":

> Our core focus is on near-term opportunities for our EpiFix and AmnioFix platforms while continuing to advance our device technologies through the regulatory process. With the acquisition of Surgical Biologics we have added technologies that do not require a 510K or PMA clearance as both the EpiFix and AmnioFix platforms are considered human tissue under Section 361 of the Public Health Services Act due to the fact that they are not more than minimally manipulated and are for homologous use only." (2011 10-K at 36).

63. On May 2, 2012 the Company issued a press release announcing its First Quarter 2012 results and reporting that revenue had increased over 250% and that the Company had achieved Positive Adjusted EBITDA for the first time in Company history as a result of sales of its newly introduced AmnioFix and EpiFix products. COO Bill Taylor stated "[d]uring the first quarter of the year we commenced the nationwide launch of AmnioFix Injectable, our newest tissue offering. AmnioFix Injectable is an allograft composed of micronized amniotic tissue…We continue to receive excellent reception and interest among physicians as we market our allografts from our two amniotic tissue technology platforms, AmnioFix and EpiFix." The press release reiterated that the Company's AmnioFix

and EpiFix products were minimally manipulated: "Our tissue technologies, processed from the human amniotic membrane, utilize our proprietary Purion® process that was developed by our wholly-owned subsidiary, Surgical Biologics, to produce a safe, effective and minimally manipulated implant for homologous use."

64. On July 26, 2012, the Company issued a press release announcing its financial results for the second quarter ended June 30, 2012. For the quarter, the Company reported net loss of $744,069, or ($0.01) diluted EPS and net sales of $4,884,256, compared to net loss of $2,503,505 or ($0.03) diluted EPS and net sales of $1,929,399 for the same period in the year prior.

65. The Company's quarterly report for the period ended June 30, 2012 (second quarter) Form 10-Q filed with the SEC stated that "The increase in revenue as compared to the prior year is due primarily to increased sales of our amniotic membrane tissue products, EpiFix and AmnioFix. The 10-Q reiterated that AmnioFix and EpiFix were minimally manipulated: "Our biomaterial platform technologies include the device technologies HydroFix® and CollaFix™, and our tissue technologies, AmnioFix® and EpiFix®. Our tissue technologies, processed from the human amniotic membrane, utilize our proprietary Purion® process that was developed by our wholly-owned subsidiary, Surgical Biologics, to produce a

safe, effective and *minimally manipulated* implant. (emphasis added).

66. The Company's quarterly report for the third quarter, issued on August 14, 2012 (Third Quarter 10-Q) similarly reported increased revenues over the prior year and quarter.

67. On October 29, 2012 the Company issued a press release announcing its financial results for the third quarter ended September 30, 2012. The press release highlighted the fact that revenue increased by more than 3.5 times over third quarter revenue for 2011, that quarter over quarter revenue increased by 63% and that gross margins hit a record level of 83%. Defendant Petit stated that "Up to this point our AmnioFix tissue grafts had provided the majority of our revenue; however we now expect sales of our EpiFix tissue grafts to show accelerated growth, especially in wound care." The press release again reiterated in is description of MiMedx that AmnioFix and EpiFix were minimally manipulated: "We process human amniotic membrane utilizing our proprietary Purion Process to produce a safe, effective and *minimally manipulated* implant for homologous use." (emphasis added).

68. On March 15, 2013 Company filed with the SEC its annual report for the fiscal year ended December 31, 2012 on Form 10-K ("2012 10-K"). The 2012

10-K was signed by Defendants Petit, Senken, and Taylor. The 2012 10-K, like the 2011 10-K, falsely stated that the Company's AmnioFix and EpiFix products do not require approval from the FDA because of an exemption under Section 361 of the Public Health Service Act and again falsely stated that AmnioFix and EpiFix were "minimally manipulated."

69. Similar statements were repeated in the Company's quarterly report for the second quarter ended June 30, 2013 filed with the SEC on August 8, 2013 on Form 10-Q. The 10-Q was signed by Defendant Senken.

70. The above statements were materially false and misleading because they misrepresented and failed to disclose the fact that the Company was in violation of the Public Health Service Act because its AmnioFix and EpiFix products required FDA approval as they did not meet the "minimal manipulation" criterion for exemption under Section 361 of the Public Health Service Act. Additionally, the Company's Third Quarter 2012 10-Q and all subsequent statements were false and misleading for the additional reason that they failed to disclose the 2012 Inspection and that the FDA was scrutinizing whether MiMedx's products were indeed 361 HCT/P's and the corresponding risk that further action by the FDA would be taken. Once MiMedx became aware that the FDA was

scrutinizing whether its products were 361 HCT/P's MiMedx had a duty to correct its unqualified statements issued prior to August 1, 2012, that assured investors that AmnioFix and EpiFix were "minimally manipulated" and were 361 HCT/P's. MidMedx's above statements issued after August 1, 2012, were false and misleading because Defendants had actual notice that the FDA was questioning the propriety of their products' Section 361 status, specifically whether the products met the "minimal manipulation" criterion. At a bare minimum, Defendants should have simultaneously disclosed to investors that CBER was closely scrutinizing the Section 361 status of AmnioFix and whether the products met the "minimal manipulation" criteria, when it asserted the products qualified for Section 361 status. As a result of the foregoing, the Company's statements were false and misleading at all relevant times.

71. On August 28, 2013, the FDA issued an "Untitled Letter" ("FDA Untitled Letter") to MiMedx and several of its distributors stating that MiMedx's AmnioFix and EpiFix Injectable products, *inter alia*, did not, as MiMedx claimed, meet all of the requirements of Section 361 of the Public Health Services Act and were therefore not subject to the Section 361 exemption and were indeed drugs and biologics products as defined under the FDCA and Public Health Services Act,

respectively. The FDA's Untitled Letter specifically noted that the products at issue did not meet the "minimal manipulation" criterion because the tissues used to manufacture the products at issue are put through the "micronization" process (i.e. are pulverized or ground up) which alters the tissue's original characteristics.

72. The FDA Untitled Letter" was the culmination of its 2012 Inspection and EIR and should have come as no surprise to Defendants.

73. On September 4, 2013 news outlets reported that the FDA had posted this letter on its website asserting that MiMedx violated the Public Health Service Act because its products required FDA approval. The FDA Untitled Letter states:

> August 28, 2013
>
> FACSIMILE & UPS EXPRESS MAIL
>
> Bill Taylor, President and CEO
> Surgical Biologics, a MiMedx Group Company
> 60 Chastain Center Blvd NW
> Kennesaw, GA 30144
>
> Dear Mr. Taylor:
>
> During a Current Good Tissue Practice (CGTP) inspection of your firm, Surgical Biologics, a MiMedx Group Company, located at 60 Chastain Center Blvd. NW, Kennesaw, GA 30144, from July 30, 2012 to August 1, 2012, investigators from the Food and Drug Administration (FDA) collected information on the manufacture of a number of amniotic/chorionic-based products. This information was provided to the FDA's Center for Biologics

Evaluation and Research (CBER) for review.

You are currently registered with the FDA to recover, screen, package, process, store, label and distribute these products. You distribute some of these products directly as a MiMedx Group Company and act as a contract manufacturer for the other products. The FDA is contacting these other distributors under separate cover. These products include: AmnioFix™ Injectable, AccelShield™ Injectable (Accel Spine), ---(b)(4)----------, and EpiFix™Injectable, all of which are intended for use, among other things, in reducing inflammation and scar tissue formation, as well as for enhancing wound healing of soft tissues.

These micronized amniotic/chorionic-based products are manufactured by ----(b)(4)------- dehydrated composite amnion and chorion tissue, and then having the end user resuspend them in normal saline for injection into soft tissues. Injectable amniotic/chorionic-based products are human cells, tissues, and cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d). ***However, these products are HCT/Ps that do not meet all of the criteria in 21 CFR 1271.10(a) and therefore are not regulated solely under section 361 of the Public Health Service Act (PHS Act) and the regulations in 21 CFR Part 1271. Specifically, the products do not meet the minimal manipulation criterion set forth in 21 CFR 1271.3(f)(1) due to the micronization process which alters the original relevant characteristics of the structural tissue, relating to the tissue's utility for reconstruction, repair or replacement. As a result, your HCT/Ps are drugs as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)].***

Please be advised that in order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312].

None of the amniotic/chorionic-based products described in this letter are the subject of an approved biologics license application (BLA), nor are there INDs in effect for any of these products. Based on this information, we have determined that your actions have violated the Act and the PHS Act.

This letter is not intended to be an all-inclusive review of the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and the PHS Act and their implementing regulations.

We request that you notify this office, in writing, of the steps you have taken or will take to address the violations noted above and to prevent their recurrence. Your response should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Suite 200 N, Rockville Maryland 20852-1448.

If you have any questions regarding this matter, you may contact Dr. Jessica Kostick at (301) 827-6201. Please be advised that only written communications are considered official.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

(emphasis added)

74. On September 4, 2013, this adverse information caused the Company's stock to fall 36% from $6.06/share to $3.85/share on extraordinary

volume.

75. MiMedx continues to market the products referenced in the FDA Untitled Letter without a biologics license. On December 4, 2013 the Company issued a press release which stated that "through a series of communications with the FDA, the FDA explained to the Company the basis for its position regarding the micronized products…The Company responded that while it does not agree with the Agency's position, it understands the Agency's interest in further regulating this emerging technology. Accordingly, the Company has proposed to the FDA that it will pursue the Investigational New Drug ("IND") and Biologics License Application ("BLA") process for certain micronized products, and, in parallel, also proposed to enter into negotiations with the FDA on a plan to transition the micronized products to licensed biological products and continue to market the products under specific conditions…If the Company and the FDA are not able to agree on a transition plan, the Company may have to remove the micronized products from the market or limit its marketing of the micronized products in some way, although it may also be able to continue to market them." (*See* December 14, 2012 Press Release: "MiMedx provides update on continuing discussions with FDA").

76. Deceitfully, Defendants publicly claimed to be surprised by the FDA Untitled Letter. In a September 5, 2013 conference call Defendant Taylor revealed that the FDA conducted a directed inspection (the 2012 Inspection) the purpose of which was to determine the status of AmnioFix as a purported 361 HCT/P. Taylor goes on to state: "The inspection report indicates the information regarding the company's AmnioFix Injectable Product which was rolled out in August 2011 was collected and forwarded to CBER, which is the Center for Biologics Evaluation and Research for review. The information collected included our advertising, packaging, processing procedures and studies conducted related to the product. Following that inspection the inspector advised us that CBER had completed its review would not be issuing a Form 483 and had no items for discussion, no non-compliance items. And therefore the inspection was classified as NAI or No Action Indicated. The formal establishment inspection report confirming the NAI conclusion then was issued on December 4, 2012. We've posted this letter on our website for review.[2]" Taylor completely misrepresents to

[2] *See* MiMedx September 5, 2013 conference call transcript ("MiMedx Group's Management Discusses FDA Untitled Letter and Reiterate Guidance," Sept. 5, 2013, 5:47:04 PM, available at http://www.nasdaq.com/aspx/call-transcript.aspx?StoryId=1676792&Title=mimedx-group-s-management-discusses-fda-untitled-letter-and-reiterate-guidance-transcript-

investors, who are unaware of the inner-workings of the regulatory process, that the fact that a Form 483 was issued and no action was indicated in no way means that the FDA inspector or CBER had approved or had drawn any conclusion as to whether MiMedx was appropriately classifying its products as 361 HCT/P's. As discussed in Paragraph 53 above, a Form 483 goes only to quality control type issues, *not* classification issues. Furthermore, the EIR does *not* confirm that the "CBER had completed its review." To the contrary, the information gathered in the 2012 Inspection Taylor refers to was forwarded to CBER, who clearly made the determination that MiMedx's products were not 361 HCT/P's as articulated in the "Untitled Letter."

77. Taylor goes on to state in the conference call that "[w]e of course believe that if there was an issue with the micronized product it would have been raised at that time." Defendants are again lying to investors because they knew full well that the 2012 Inspection was conducted to gather data - not to make a conclusion-, in the same way that turning over documents to the IRS for an audit means that the audit is pending, not that a determination has been made.

78. On January 6, 2014, at a presentation at the JPMorgan Healthcare Conference, CEO Petit stated that "it's clear that the FDA is taking a new position

where they want to regulate this micronized amnion differently than what they have in the past.[3]" It is patently false for the Company to suggest that the FDA is taking a "new position," as the FDA has never taken *any* position on how it has regulated micronized amnion. This statement is yet another attempt by MiMedx to whitewash the fact that it knowingly manufactured and marketed, and *continues* to manufacture and market products that do not meet the criteria for exemption from classification as biologics under Section 361.

D. Additional Facts Probative of Scienter

79. The intense premarket scrutiny associated with a product that is considered a drug or biologic because it does not satisfy all of Section 361's requirements can include over a decade of expensive research, with no guarantees that the drug will ever be approved.

80. While MiMedx claims to screen its tissue-based products for diseases and put them through a purification process, tissue based products that are more than minimally manipulated can pose safety concerns. London based FDA regulatory consultant Christopher Bravery stated, with respect to the "minimal

3 *See* MiMedx Group's CEO Presents at JPMorgan Healthcare Conference, January 6, 2014, transcript available at: http://www.nasdaq.com/aspx/call-transcript.aspx?StoryId=1950701&Title=mimedx-group-s-ceo-presents-at-jpmorgan-healthcare-conference-transcript-

manipulation" category that "the concern is product safety risks could arise when a tissue's properties are altered too much." *See MiMedx*, Sara Germano, Sept. 11, 2012, Wall Street Journal. Defendant Petit dismissed this concern stating that "'Mother Nature did the safety and efficacy trials on this tissue long ago.'" *Id*.

81. Neither Defendant Petit nor the other members of MiMedx Board of Directors has any background in medicine or biology, not to mention biologics or tissue-based products such as AmnioFix and EpiFix, and are not qualified to opine on whether AmnioFix and EpiFix products meet the "minimal manipulation" criterion of Section 361.

82. According to MiMedx's website, Randall Spencer is the Vice President of Clinical Innovation at MiMedx and has extensive experience with tissue regulation. Mr. Spencer has been in the bioimplant industry since its infancy, with over 23 years of experience. Mr. Spencer "made significant contributions to the development of a wide range of products which are now considered the standard of care for certain surgical procedures." Spencer is also the co-founder of Surgical Biologics, (which was founded in 2006). According to MiMedx's website, Spencer "has been a pioneer in the development of the latest advances in processing amniotic membrane tissue." When MiMedx acquired

Surgical Biologics in 2011 Mr. Spencer served as the Director of Product Development until March 2013 when he assumed his current role of Vice President of Clinical Innovation.

83. According to MiMedx's website, Frank Burrows, Vice President of Corporate Strategy at MiMedx, joined MiMedx in 2011. He joined the Company in April 2011 as Vice President of Wound Care and led the marketing of the Company's wound care offerings. He has a long track record of working in the FDA-regulated industry and is experienced with tissue-based products. He became Vice President of Global Marketing in August 2011 and focused on expanding the Company's presence in the regenerative tissue market.

84. Based on their experience and backgrounds Messrs. Spencer and Burrows would have known that MiMedx's method of manufacturing AmnioFix and EpiFix, which consisted of chopping the tissue membrane into little pieces, would have rendered the tissue no longer minimally manipulated and thus not subject to regulations solely as a Section 361 HCT/P's.

85. Ms. Chew believes that this should be common knowledge by anyone familiar with this type of tissue processing, (i.e. micronization) that the

micronization process by definition renders a product more than "minimally manipulated."

86. Defendants' statements that AmnioFix and EpiFix qualified as Section 361 HCT/P's were knowingly false because Defendants' either knew that they were false or knew that they were made without a reasonable basis. Defendants knew that they were under scrutiny by the FDA with respect to their classification of their products as 361 HCT/P's as of the Inspection in July 2012, yet they failed to inform investors of the risks associated with the 2012 Inspection (i.e. that the FDA might disagree with their classification).

87. As Ms. Chew points out, common sense suggests that pulverizing a tissue significantly "alters the original relevant characteristics of the tissue."

88. After issuing the FDA Untitled Letter the FDA further explained that MiMedx's micronized products were more than minimally manipulated because "[c]ryo-milling cut, dehydrated amniotic/chorionic membrane results in a micron-sized powder and the loss of the tensile strength and elasticity that are essential characteristics of the original amniotic/chorionic tissue relating to its utility to function as a physical membrane (i.e. covering, barrier)."

89. When a product is ground up or put through "cryo-milling" it is no longer a cell, it is a mixture of proteins or ground up tissue. According to the aforementioned Britain-based regulatory consultant interviewed by Plaintiff's investigator, a regulatory professional with experience in biologics should have been able to easily conclude that the micronized tissues would be regulated as a biologic (and not a Section 361 HCT/P) and therefore require clinical trials under IND, and a BLA before marketing. The consultant further stated that a life sciences lawyer should have been able to reach this conclusion and if doubt existed the Company could have and should have requested advice and a determination (classification) from the FDA for free.

90. In short, it was obvious to Defendants that MiMedx's products did not qualify under Section 361 HCT/P and that Defendants were required to obtain FDA approval of their products prior to their sale.

CLASS ACTION ALLEGATIONS

91. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers of the securities of MiMedx during the Class Period (the "Class"). Excluded from the Class are Defendants and their families, the officers and directors of the Company,

at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

92. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, MiMedx common stock and other publicly traded securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by MiMedx or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

93. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

94. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

95. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the Exchange Act was violated by Defendants as alleged herein;

(b) whether statements made by Defendants misrepresented material facts about the business, operations and management of MiMedx; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

96. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

APPLICATION OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

97. The market for MiMedx's shares was open, well-developed and efficient at all times during the Class Period permitting Plaintiff a presumption of reliance on the integrity of the market for MiMedx's stock.

98. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(a) The omissions and misrepresentations were material;

(b) The Company's stock traded in an efficient market;

(c) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(d) Plaintiff and other members of the Class purchased MiMedx common stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

99. The market for MiMedx's securities was an efficient market during the Class Period for the following reasons among others:

(a) MiMedx's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient automated market;

(b) As a regulated issuer, MiMedx filed periodic public reports with the SEC, and/or NASDAQ;

(c) MiMedx regularly communicated with investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major news wire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

(d) MiMedx was followed by securities analysts including Northland Securities, Lake Street Capital Markets, Ascend Capital and Cannacord Genuity and other brokerage and research firms who wrote research reports about the Company, and these reports were distributed widely;

(e) MiMedx met the requirements to and did file an S-3 registration statement during the Class Period;

(f) According to MiMedx's Form 10-Q filed with the SEC on August 14, 2012 there were 83,063,139 shares of MiMedx common stock outstanding as of July 31, 2012;

(g) On average, approximately 1.71 million shares of MiMedx's stock were traded on a weekly basis during the Class Period. Thus, approximately 2.06% of MiMedx's 83,063,139 outstanding shares of common stock were traded on a weekly basis during the Class Period;

(h) Unexpected material public news concerning MiMedx was rapidly reflected in MiMedx's share price.

100. As a result of the foregoing, the market for MiMedx's securities promptly digested current information regarding MiMedx from all publicly available sources and reflected such information in MiMedx's stock price.

COUNT I

For Violations of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

101. Plaintiff incorporates the above allegations as if fully set forth herein.

102. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

103. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of MiMedx common stock during the Class Period.

104. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for MiMedx common stock. Plaintiff and the Class would not have purchased MiMedx common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

COUNT II

For Violations of §20(a) of the Exchange Act Against All Defendants

105. Plaintiff incorporates the above allegations as if fully set forth herein.

106. The Individual Defendants acted as controlling persons of MiMedx within the meaning of §20(a) of the Exchange Act. By reason of their positions with the Company, and their ownership of MiMedx stock, the Individual Defendants had the power and authority to cause MiMedx to engage in the wrongful conduct complained of herein. MiMedx controlled the Individual Defendants and all of the Company's employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and the Rosen Law Firm as Lead Counsel and The Antonino Firm LLC as Liaison Counsel;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: January 27, 2014

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

s/ Philip Kim, Esq.
Phillip Kim, Esq. (admitted *pro hac vice)*
Laurence M. Rosen, Esq.
275 Madison Avenue, 34th Floor
New York, NY 10016
Phone: (212) 686-1060
Fax: (212) 202-3827
pkim@rosenlegal.com
lrosen@rosenlegal.com

Lead Counsel for Plaintiff

and

s/ Lauren S. Antonino, Esq.
Ga. Bar No. 652408
Attorney for Lead Plaintiff Movant Tim Kelly
The Antonino Firm LLC

Five Concourse Parkway
Suite 1425
Atlanta, Georgia 30328
Tel: 770-408-1229
Fax: 866-372-5586
lauren@antoninofirm.com

Liaison Counsel for Plaintiff

EXHIBIT 1

NANCY CHEW, M.S., RAC FRAPS

EDUCATION

M.S. Physiology
Florida State University 1968
B.A. Biology
Woman's College of the University of North Carolina 1963

POST-GRADUATE STUDY

Pre-doctoral graduate programs:
Pharmacology and Toxicology
St. John's University 1982 - 1987

Biochemistry
Cornell University Medical College, Graduate School of Medical Sciences 1968 - 1969

Biochemistry
Bowman Gray School of Medicine 1963 - 1964

HONORS AND AWARDS

Appointed to North American Leadership Team, TOPRA	2010 - 2013
Elected RAPS Fellow	2009
Appointed to RAPS Fellows Selection Committee	2010 - 2013
Invited reviewer, American Association for the Advancement of Science	
Research Competitiveness Program for:	
Michigan 21st Century Jobs Fund	FY 2006
Michigan Technology Tri-Corridor Fund Competition;	FY 2005
Michigan Life Sciences Corridor Company Formation Fund;	FY2003
Appointed to Scientific Advisory Board, BioLink Life Sciences, Inc.	2004 - Present
Appointed as Adjunct Professor, Campbell University School of Pharmacy	2003 – 2005
Awarded the Leonard J. Stauffer Award for Mentoring, RAPS and RACB	1998
Elected President, North Carolina Regulatory Affairs Forum	1997
Elected Chair, North Carolina Regulatory Affairs Forum	1996
Appointed to the Scientific Advisory Board, AeroGen Incorporated	1996 - 1999
Appointed Member, Regulatory Affairs Certification Board,	
Regulatory Affairs Professional Society (RAPS)	1994 - 1997
Awarded the Regulatory Affairs Certified Credential, Regulatory Affairs	
Certification Board	1991
Appointed Chair of Credentialing Board, RAPS	1988 - 1989
Elected Board of Directors, RAPS	1987 - 1988
Awarded "R.E. Greco Regulatory Affairs Professional," RAPS	1986
Received Special Recognition Award for Educational Programs, RAPS	1986
Elected Vice-President, Education and Membership, RAPS	1984 – 1986
Awarded Cornell University Predoctoral Fellowship	1968 - 1969
Awarded Public Health Service Predoctoral Fellowship, National Institute	
of General Medical Sciences	1966 - 1968
Awarded Florida State University Teaching Fellowship	1965 - 1966
Awarded NDEA Title IV Predoctoral Fellowship in biochemistry	1963 - 1964

BUSINESS BACKGROUND

Merged Quotidian Incorporated and Regulatory Affairs, North America LLC	2009
Sold partnership in Apidex LLC	2001
Founding partner, Apidex, LLC	1999
Founded Regulatory Affairs, North America LLC	1997
Founded Quotidian Incorporated	1997
Sold NJC Enterprises, Ltd. to Pharmakopius International, plc	1996
Founded NJC Enterprises, Ltd.	1976

PROFESSIONAL BACKGROUND

Regulatory Affairs, North America, Inc. January 2009 – Present
Regulatory Affairs, North America LLC July 1997 – December 2008
President

Regulatory affairs consulting includes product development advice, licensing assessments, regulatory liaison with FDA, regulatory research, analysis, and opinion. Regulatory services include building and managing ad hoc teams to meet specific regulatory needs such as product development/regulatory strategy, technical evaluation of data, FDA meetings, and submissions development. Heads a consortium of veteran regulatory affairs practitioners: business development, general management, strategic planning, and client liaison.

Pharmakopius International, plc 1996 – 1997
Director, Worldwide Regulatory Affairs
and
NJC Enterprises, Ltd. 1976 - 1996
Founder and President

Regulatory affairs and biomedical product development consultant. Procured and managed contracts, advised clients regarding regulatory affairs, represented clients on regulatory matters. Provided regulatory presence on product development teams. Reviewed client procedures and documentation. Researched regulatory issues. Reviewed, analyzed, compiled, and synthesized chemistry, manufacturing and controls, preclinical and clinical research data. Prepared and delivered submissions (dossiers) for New Drug, Investigational New Drug, Product License, Establishment License Applications, Master Files, Premarket Notification [510(k)] submissions, clinical investigator brochures, and corresponding non-U.S. registration documents, response letters, position papers, articles for publication, monographs, and reviews. Developed customized literature searches. Developed Good Laboratory Practice Programs.

Freelance Medical Writer/Researcher 1974 - 1976

Prepared monographs, clinical reports, scholarly articles, book chapters and magazine features for publishing companies, pharmaceutical manufacturers, advertising agencies, and clinical researchers.

Hoffman-LaRoche, Inc. 1971 – 1974
Assistant Biochemist

Carried out independent research projects on progesterone metabolism in early and mid-gestational mouse embryos. Project involved tissue culture, microdissection, surgery, radioimmunoassay, chromatography, and radioisotope counting methods. Wrote and presented research reports. Responsible for maintenance of laboratory equipment and supplies. Supervised one animal technician.

Population Council, Rockefeller University 1970 - 1971
Technician

Implemented protein binding progesterone assay for investigation of LH involvement in pregnancy. Carried out immunology studies on the effect of steroid hormones on postnatal development, maturation, and reproductive capacity. Participated in research training program for medically educated postdoctoral fellows.

Orentreich Foundation for the Advancement of Science 1969 - 1970
Senior Research Technician

Developed and implemented hydroxyproline assay for study of collagen in aging skin.

Rockefeller University 1964 - 1965
Technician

Laboratory of Christian DeDuve. Studied the influence of glucagon on the formation and properties of cytolysomes using biophysical and biochemical techniques.

PUBLICATIONS

Research:

Chew, N. J. and Sherman, M.I. 1975. Biochemistry of Differentiation of Mouse Trophoblast: Δ5, 3 β-Hydroxysteroid Dehydrogenase. Biology of Reproduction 12:351-359.

Marcal, J. M., **Chew, N. J**., Salomon, D. S., and Sherman, M. I. 1975. Δ5, 3 β-Hydroxysteroid Dehydrogenase Activities in Rat Trophoblast and Ovary During Pregnancy. Endocrinology 96(5):1270-1279.

Sherman, M. I. and **Chew, N. J.** 1972. Detection of Maternal Esterase in Mouse Embryonic Tissues. Proc. Nat. Acad. Sci. 69(9): 2551-2555.

Chew, N. J. and Sherman, M. I. 1973. Δ5, 3 β-Hydroxysteroid Dehydrogenase Activity in Mouse Giant Trophoblast Cells *In Vivo* and *In Vitro*. Delivered at the Society for the Study of Reproduction Meetings, August 14, 1973, University of Georgia, Athens, Georgia.

Chew, N. 2000. Aerosolized Drugs: Current Regulatory Perspective. Resp Care 45(6): 764 –768.

Von der Leyen, H.E. and **Chew, N.** 2005. Nitric oxide synthase gene transfer and treatment of restenosis: from bench to bedside. Review Article. Eur J Clin Pharmacol. 21 (Oct): 1-7.

BOOK CHAPTER:

Chew, N. and Cavagnaro, J.A. "Regulatory Issues in Gene Therapy. Good Science – Good Sense." In: Manufacturing of Gene Therapeutics: Methods, Processing, Regulation And Validation. Ed. G. Subramanian (London, U.K.: Kluwer Academic/Plenum Publishers, 2002).

MAGAZINE ARTICLES, COLUMNS, AND EDITORIAL BOARDS:
Applied Clinical Trials
BioPharm (Editor, Regulatory Affairs Column, monthly March 1988 – December 2002)
BioProcess International, Editorial Advisory Board (October 2002 – May 2005)
BioProcess International, Editorial Advisory Board (Jan 2010 – Present)
Contemporary Ob/Gyn
Contemporary Surgery
Medical World News
Pharmaceutical Manufacturing Review (U.K.)
Pharmaceutical Technology Europe
Regulatory Affairs Focus
Regulatory Rapporteur
The Physician and Sports Medicine

PROFESSIONAL MEMBERSHIPS

American Association for the Advancement of Science
American College of Toxicology
Drug Information Association
Food and Drug Law Institute
North Carolina Regulatory Affairs Forum
Regulatory Affairs Professionals Society (RAPS)
The Organization for Professionals in Regulatory Affairs (TOPRA)

EXHIBIT 2

Guidance for Industry and FDA Staff:

Minimal Manipulation of Structural Tissue Jurisdictional Update

For questions regarding this document, contact:
Suzanne O'Shea, Office of Combination Products at 301-427-1934 or
Office of Cellular, Tissue and Gene Therapies, Tissue Reference Group at 301-827-6176.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of Combination Products
and
Center for Biologics Evaluation and Research
September 2006

Guidance for Industry and FDA Staff:

Minimal Manipulation of Structural Tissue Jurisdictional Update

Additional copies are available from:

Office of Combination Products
Office of the Commissioner
Food and Drug Administration
15800 Crabbs Branch Way, Suite 200 (HFG-3), Rockville, MD 20855
(Tel) 301-427-1934, (Fax) 301-427-1935
Internet: http://www.fda.gov/oc/combination
Email: combination@fda.gov

or

Office of Communication, Training and
Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
(Tel) 800-835-4709 or 301-827-1800
Internet: http://www.fda.gov/cber/guidelines.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of Combination Products
and
Center for Biologics Evaluation and Research
September 2006

Guidance for Industry and FDA Staff:

Minimal Manipulation of Structural Tissue Jurisdictional Update

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Contains Nonbinding Recommendations

TABLE OF CONTENTS

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Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. PURPOSE

This guidance is intended to improve the transparency of FDA's jurisdictional determinations by providing additional information about the classification and assignment of a certain class of products. The jurisdictional information contained in this guidance document may be based on a past decision made in response to a Request for Designation (RFD) submitted pursuant to 21 CFR Part 3, or in response to a request for an informal jurisdictional determination. FDA's Office of Combination Products (OCP) issues jurisdictional updates on selected classes of products on an ongoing basis. OCP selects product classes to be the subject of jurisdictional updates based on its perception of the current level of interest in the jurisdictional issue, the extent to which the class of products can be clearly described, the extent to which the existence and description of the class of products has been made public, and related factors.

This guidance document provides information about the classification of products as human cells, tissues and cellular and tissue-based product (HCT/P's) regulated solely under section 361 of the Public Health Service Act (PHS Act). Specifically, this guidance document discusses FDA's current thinking on the meaning of the phrase "minimally manipulated" contained in 21 CFR 1271.10(a)(1), and defined ("minimal manipulation") at 21 CFR 1271.3(f), as it applies to structural tissue. OCP and the Center for Biologics Evaluation and Research are jointly issuing this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. JURISDICTIONAL INFORMATION

FDA's regulations set forth the criteria that must be met for an HCT/P to be regulated solely under section 361 of the PHS Act. These criteria are that the HCT/P must:

- be minimally manipulated;
- be intended for homologous use only, as reflected in the labeling, advertising, or other indications of the manufacturer's objective intent;
- not be combined with a drug or device, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of the water, crystalloids, or sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
- not have a systemic effect and not be dependent on the metabolic activity of living cells for its primary function except if for autologous use, allogeneic use in a first-degree or second-degree blood relative, or reproductive use.[1]

FDA regulations further define "minimal manipulation" for structural tissue as "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement."[2]

FDA has received several RFD's requesting a determination of whether or not certain HCT/P's will be regulated solely under section 361 of the PHS Act based on the manipulation the product undergoes during processing.[3] For purposes of determining whether a structural tissue product is minimally manipulated, a tissue characteristic is "original" if it is present in the tissue in the donor. A tissue characteristic is "relevant" if it could have a meaningful bearing on how the tissue performs when utilized for reconstruction, repair, or replacement. A characteristic of structural tissue would be relevant when it could potentially increase or decrease the utility of the original tissue for reconstruction, repair or replacement.

Accordingly, FDA's determination of whether structural tissue is eligible for regulation solely under section 361 of the PHS Act has encompassed a consideration of all the potential effects, both positive and negative, of the alteration of a particular characteristic on the utility of the tissue for reconstruction, repair or replacement, i.e., changing the

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[1] 21 CFR 1271.10(a).

[2] 21 CFR 1271.3(f)(1). For cells or nonstructural tissue, minimal manipulation is processing that does not alter the relevant biological characteristics of cells or tissues. 21 CFR 1271.3(f)(2).

[3] FDA has formed a committee known as the Tissue Reference Group (TRG) consisting of representatives from the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Office of Chief Counsel, and the Office of Combination Products to make initial recommendations on several issues pertaining to HCT/P's, including whether the product may be regulated solely under section 361 of the PHS Act. TRG recommendations may be appealed through the Request for Designation process, as outlined in 21 CFR Part 3. Further information about the TRG may be found at http://www.fda.gov/cber/tissue/tisrefgrp.htm.

characteristic could improve or diminish the tissue's utility. Once FDA has determined, based on the data and information before it, that processing has altered an original characteristic of a structural tissue, and that the characteristic is relevant in that it has a potential effect on the utility of the tissue for reconstruction, repair, or replacement, the agency has considered the tissue to be more than minimally manipulated and not eligible for regulation solely under section 361 of the PHS Act.[4] In such a case the structural tissue will be regulated as a drug, device and/or biological product under the Federal Food, Drug, and Cosmetic Act and/or section 351 of the PHS Act.[5]

III. FOR FURTHER INFORMATION

For an initial determination whether a particular HCT/P will be regulated solely under section 361 or regulated as a drug, device or biological product, contact:

Office of Cellular, Tissue and Gene Therapies
Tissue Reference Group[6]
Telephone: 301-827-6176

The Office of Combination Products may also be contacted at

Suite 200, HFG-3
15800 Crabbs Branch Way
Rockville, Maryland 20855
Telephone: 301-427-1934
e-mail: combination@fda.gov

A formal determination of the classification or assignment of a particular product may be made through the Request for Designation (RFD) process. Further information about the RFD process is available at 21 CFR Part 3, www.fda.gov/oc/ombudsman/part3&5.htm and in the document "Guidance for Industry and FDA: How to Write a Request for Designation (RFD)," available at www.fda.gov/oc/combination/. We recommend that sponsors call OCP at 301-427-1934 to discuss their particular situation before submitting an RFD.

OCP is always available as a resource to you. We encourage you to contact OCP if you have any questions about the jurisdiction of your product.

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[4] 21 CFR 1271.10
[5] 21 CFR 1271.20
[6] Further information about FDA's regulation of HCT/P's and the Tissue Reference Group may be found at http://www.fda.gov/cber/tiss.htm.

EXHIBIT 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

December 4, 2012

Bill Taylor
President and CEO
Surgical Biologics, LLC.
60 Chastain Center Blvd NW
Kennesaw, GA 30144

Dear Mr. Taylor:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises on July 30 – August 1, 2012 by Investigator Kimberly Delk-Brooks of the U.S. Food and Drug Administration (FDA). This report is being provided to you for information purposes. This procedure is applicable to EIRs for inspections conducted on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report. This copy may also reflect redactions made by the Agency in accordance with the FOIA and Title 21, Code of Federal Regulations, Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there are any questions about the released information, feel free to contact Marie Mathews, Compliance Officer, at (404) 253-1279 or write to the address noted in the letterhead.

Sincerely,

John R. Gridley, Director
Atlanta District

Establishment Inspection Report	FEI:	**3005897621**
Surgical Biologics LLC	EI Start:	07/30/2012
Kennesaw, GA 30144-5598	EI End:	08/01/2012

TABLE OF CONTENTS

SUMMARY OF FINDINGS

The previous inspection of this Human Cells, Tissues, and Cellular Tissue-Based Products (HCT/Ps) firm was an initial inspection conducted on 2/28-3/1/11 and classified as No Action Indicated (NAI). There were no items of discussion brought forth. Form FDA 483 - Inspectional Observation was not issued.

The current inspection was a directed inspection conducted on 7/30-8/1/12, in response to ATL-DO FY12 FACTS Assignment: 1417765 (PAC 41002D) in accordance with Compliance Program 7341.002 – Inspection of Human Cells, Tissues, and Cellular Tissue-Based Products (HCT/Ps). The assignment was issued as a result of an inspection conducted by LOS-DO regarding inadequate summary of records being forwarded by this firm to distributors. Additionally, follow up was requested by CBER to determine the status of the firm's Amniofix injectable product. A limited inspection was required to evaluate the firm's compliance. The FDA 482 was issued to Bill Taylor, President and CEO.

The current inspection found that the firm continues to recover human tissue – specifically amniotic membrane, which undergoes further processing into implantable grafts. Since the previous inspection, the firm has begun manufacturing four injectable products using amniotic membrane. The firm has also moved manufacturing into a larger facility across the street from their administrative offices. There have been several changes to management as well as changes to distributors and the discontinuation of several products since the previous inspection. This was a limited inspection that did not include GMP review of the firm's recovery, processing and distribution operations. No refusals were encountered during the inspection. No samples were collected.

An FDA 483 - Inspectional Observation was not issued at the conclusion of this inspection. There were no items of discussion brought forth during the close-out discussion with management and the inspection was classified as NAI.

Establishment Inspection Report	FEI:	**3005897621**
Surgical Biologics LLC	EI Start:	07/30/2012
Kennesaw, GA 30144-5598	EI End:	08/01/2012

ADMINISTRATIVE DATA

Inspected firm:	Surgical Biologics LLC
Location:	60 Chastain Center Blvd NW Kennesaw, GA 30144-5598
Phone:	404-461-9267
FAX:	
Mailing address:	60 Chastain Center Blvd NW Kennesaw, GA 30144-5598
Dates of inspection:	7/30/2012, 7/31/2012, 8/1/2012
Days in the facility:	3
Participants:	Kimberly C. Delk-Brooks, Investigator

At the initiation of the inspection on 7/30/12, I presented credentials and issued an FDA-482, Notice of Inspection to Mr. Bill Taylor, President and CEO (**Attachment 1**).

This directed, limited assignment was issued as a result of an inspection conducted by LOS-DO regarding inadequate summary of records being forwarded by this firm to distributors (**Attachment 2**). Additionally, follow up was requested by CBER to determine the status of the firm's Amniofix injectable product. A limited inspection was required to evaluate the firm's compliance.

The current inspection found that the firm continues to recover human tissue – specifically amniotic membrane, which undergoes further processing, via the firm's trademarked Purion process, into implantable grafts. The Purion process includes wet processing, dehydration and sterilization of amniotic membranes. A copy of the firm's procedure is attached (**Exhibit KDB 1-3**).

There have been several changes to the firm's operations since the previous inspection. The firm launched their Amniofix injectable product (as well as 3 private label versions for distributors) approximately 3-4 months after the conclusion of the previous inspection (on or about August 2011). Also, the Mimedix Group, which is the parent company of Surgical Biologics relocated from their Marietta, GA office to the Chastain Center Blvd location in Kennesaw. All of the Mimedix Group and Surgical Biologics administrative offices are now located at the Chastain Center Blvd location. Additionally, the firm [redacted] and moved all of their human tissue product manufacturing, effective May 21, 2012. The tissue manufacturing facility is 20,000 sq ft and is located across the street from the administrative offices. It previously housed the firm's medical device manufacturing and is located at:

300 Town Park Dr
Ste 260
Kennesaw, GA 30144

There have also been several changes to management since the previous inspection. The firm's VP of Regulatory Affairs and Quality Assurance, [redacted], is no longer with the company as of November 2011. He was replaced by [redacted]. Surgical Biologics' President, John Daniel, is transitioning into a consulting role with the company. He has been replaced by Bill Taylor, who now serves as President and CEO of Surgical Biologics and MiMedix Group. The firm's Medical Director continues to be Dr. Don Fetterolf and their Science Officer is Dr. Tom Koob.

The firm has also discontinued manufacturing of several human tissue products including BioCover and AmnioClear, formally distributed by Snowasis Medical and AFCell Medical, respectively. A listing of the products that the firm currently manufactures and the associated private label distributors are attached (**Exhibit KDB 4**). A list of all of the firm's consignees was also collected and is attached (**Exhibit KDB 5**).

The firm continues to use [redacted] Inc located in Minnetonka, MN for infectious disease testing. There have been no changes to the companies used for graft irradiation/sterilization, which include [redacted] out of San Diego, CA; [redacted] located in Charlotte, NC; and [redacted] in Haw River, NC. The firm continues to be AATB certified with recertification occurring this past January 2012. There have been no changes to the firm's manufacturing coding system. Each donor and subsequent grafts manufactured from the donor tissue are all assigned a unique code and are individually tracked, and able to be linked to one another.

Information regarding the firm's Amniofix injectable product, which was rolled out approximately August 2011, was collected and forwarded to CBER for review. The information collected included advertising, packaging, processing procedures and studies conducted related to the product (**Exhibit KDB 6-12**). The firm manufactures a total of four injectable products made from amniotic membrane, which undergo the same processing as all of their other amniotic membrane graft products. Once the membrane sheet has been dehydrated, it will undergo cryo milling in order to grind the membrane down into micronized pieces. The cryo milling requires that the firm freeze the membrane for a specified period of time and spin it in a mill, using cutting balls to cut the membrane into small pieces. The understanding is that by freezing the membrane first, the heat generated during the cutting process will not denature the proteins in the membrane. The firm considers their processing technique to be minimal manipulation of the tissue and results in no viable cells after processing.

The product is placed in a sterile vial and sent for sterilization after final packaging in an inner and outer pouch takes place. The product is intended to aid in the "reduction of inflammation and enhancement of soft tissue healing, solely in soft tissue areas." This includes "tendon tissue and applications where tendon tissue is inflamed due to micro tears in the tissue." The injectable product

is reconstituted using Normal Saline per the "Instructions for Use" brochure included with the product. The injectables have a shelf life of five years and are to be stored at room temperature.

A review of the Summary of Records and other packaging (**Exhibit 13-16**) that accompanies each graft and injectable product manufactured by the firm was conducted. No discrepancies related to the firm's Summary of Records were noted. The firm includes a "Summary of Records" card that is included with each graft or injectable product which meets the requirements of 21 CFR 1271.55(b) (**Exhibit KDB 17**):

1. A statement that the communicable disease testing was performed by a laboratory:
    a. Certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988.
    b. That has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions;
2. A listing and interpretation of the results of all communicable disease tests performed.
3. The name and address of the establishment that made the donor-eligibility determination;
4. In the case of an HCT/P from a donor who is ineligible based on screening and released under paragraph (b) of Sec 1271.65, a statement noting the reason(s) for the determination of ineligibility.

Item number four does not apply as the firm does not use tissue from ineligible donors. The firm's "Instructions for Use" (**Exhibit KDB 18**), which is also included within the product packaging, does not include the Summary of Records information as mentioned in the LOS-DO EIR. I discussed with the firm the possibility of adding the Summary of Records information to the "Instructions for Use" brochure to reduce the amount of documents that must be included with the grafts and/or injectable products. This way they would be better able to ensure that the Summary of Records always accompanies the product and be able to reduce the likelihood of the graft, "Instructions for Use" brochure and the Summary of Records card being separated. Management stated that they would consider making changes to their brochure but did not commit to doing so because they are currently in compliance through use of the Summary of Records card.

I also discussed with the management information received by CBER indicating that their Amniofix injectable product is being marketed for use with their Epifix graft. According to the firm, the two products are not intended to be marketed or used in conjunction with one another. I inquired if they provide any specific training to their distributors regarding the intended use of the products, as well as what is included within the product packaging. They stated that they do not currently provide that type of training.

Prior to the conclusion of the inspection, management confirmed revisions to their procedures that would provide additional instruction and clarification in the aforementioned areas. The revised SOPs

were to be completed by close of business 8/2/12. Management stated that training on the revised procedures would take place during the month of August 2012.

DISCUSSION WITH MANAGEMENT

A close out meeting was held with management on 8/1/12. The following individuals were present:

Bill Taylor, Present and CEO
[redacted], Director Quality Assurance
Parker "Pete" Pettit, Chairman Mimedix Group
[redacted], VP of Regulatory and Quality

An FDA 483 was not issued at the conclusion of the inspection. No items of discussion were brought forth during the close out meeting with management. I thanked management for their time and cooperation. [redacted] inquired about the time frame for receiving a copy of the EIR, to which I advised 6-8 weeks. With no further questions from management, the inspection was concluded.

All FMD-145 correspondence should be addressed to:

Bill Taylor, President and CEO
Surgical Biologics, LLC
60 Chastain Center Blvd NW
Kennesaw, GA 30144

EXHIBITS COLLECTED

Exhibit KDB 1: Copy of Amnion/Chorion Processing and Decontamination [redacted]
Exhibit KDB 2: Copy of Process Record – Amnion/Chorion Processing [redacted]
Exhibit KDB 3: Copy of Dehydration of Amnion Products [redacted]
Exhibit KDB 4: Listing of the firm's Distributors of Private Label Products [redacted]
Exhibit KDB 5: Copy of the firm's consignee list [redacted]
Exhibit KDB 6: Copy of the firm's Amniofix Injectable Advertising [redacted]
Exhibit KDB 7: Copy of Micronized Amnion/Chorion Processing [redacted]
Exhibit KDB 8: Copy of Process Record – Micronized Amnion/Chorion Processing [redacted]
Exhibit KDB 9: Copy of Product Specification – Micronized Amnion/Chorion Product (AI-) [redacted]

Exhibit KDB 10: Copy of the firm's USP Monograph for Human Dehydrated Amniotic Membrane [redacted]

Exhibit KDB 11: Copy of the firm's Micronized Amnion Growth Factor IHC Evaluation Study [redacted]

Exhibit KDB 12: Copy of the firm's Competitive Tissue Analysis for Purion Processed Dehydrated Human Amniotic Membrane products [redacted]

Exhibit KDB 13: Example of Amniofix Injectable Packaging [redacted]

Exhibit KDB 14: Example of Amniofix Graft Packaging [redacted]

Exhibit KDB 15: Example of Epifix Graft Packaging [redacted]

Exhibit KDB 16: Examples of product labeling placed on the exterior to packaging [redacted]

Exhibit KDB 17: Example of the firm's Summary of Records Card [redacted]

Exhibit KDB 18: Example of the firm's Instructions for Use [redacted]

ATTACHMENTS

Form FDA 482 – Notice of Inspection, issued 7/30/12

Memo from LOS-DO regarding Inadequate HCT/P summary of records provided by manufacturer to distributors

Kimberly C. Delk-Brooks, Investigator